U.S. Department of Justice

United States Attorney
Northern District of Ohio

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December 21, 2018

Enu Mainigi
Williams and Connolly LLP
725 Twelfth Street, NW
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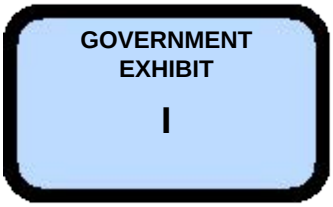
Linda Singer
401 Ninth Street, NW, Suite 1001
Washington, DC 20004

Re: *Touhy* Requests in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio)

Dear Counsel:

By letter dated July 10, 2018, the defendants in the above-captioned matter (the Defendants) requested 30(b)(6) testimony from the United States Drug Enforcement Administration (DEA), under the Department of Justice (DOJ's) *Touhy* regulations, 28 C.F.R. § 16.21, *et seq*. The Defendants' 30(b)(6) testimony *Touhy* request was later modified on October 17, 2018, when the Defendants agreed to limit the topics on which 30(b)(6) testimony was requested, and provided further detail on the information encompassed within each topic. Additionally, on December 11, 2018, the plaintiffs in the above-captioned matter (the Plaintiffs) requested 30(b)(6) testimony from the DEA under the DOJ's *Touhy* regulations. This letter summarizes DOJ's response to the Defendants' narrowed 30(b)(6) *Touhy* request and the Plaintiffs' 30(b)(6) *Touhy* request.

As you are aware, federal regulations govern the disclosure of official DEA information by federal employees. *See U.S. ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951); *United States v. Wallace*, 32 F.3d 921, 929 (5th Cir. 1994). Under these regulations, current and former DEA employees are prohibited from disclosing official information in proceedings in which the United States is not a party without express authorization from the DOJ. *See* 28 C.F.R. 16.22(a). "[N]either FOIA nor a third-party subpoena will provide the private litigant with guaranteed access, at public expense, to the testimonial evidence of agency employees. When the government is not a party, the



decision to permit employee testimony is committed to the agency's discretion." *COMSAT Corp. v. Nat'l Sci. Found.*, 190 F.3d 269, 278 (4th Cir. 1999).

After careful consultation with the DEA, I have determined that your request for the disclosure of official government information should be granted in part and denied in part. Specifically, I am authorizing the 30(b)(6) testimony below and have identified the DEA witnesses who will provide that testimony. In light of the Court's determination in its Order Establishing Deposition Protocol (Dkt. 643) that party 30(b)(6) depositions should be limited to 14 hours[1], these witnesses are authorized to testify for no more than 14 hours collectively, and no single witness' deposition shall exceed more than seven hours. We request that the Plaintiffs and Defendants reach an agreement on the division of the 14 hours between the two sides.

The two parties have requested deposition testimony as follows:

Topics from Defendants:

Topic 2: Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

- DEA's policies, practices, and guidance relating to whether registrants are permitted to ship orders of controlled substances that the registrant determines to be "suspicious" and/or "excessive," including the nature of the purported duty to conduct due diligence on such orders, as described in the 2006 and 2007 letters from DEA to registrants, and any changes to those policies, practices, and guidance over time;

- DEA's interpretation of, and policies and practices relating to, what constitutes a "suspicious order" under 21 C.F.R. § 1301.74(b), and any changes thereto over time;

- DEA's interpretation of, and policies and practices relating to, registrants' obligations to "know their customers" and/or "know their customers' customers," and any changes thereto over time;

- DEA's communications with third parties concerning potential amendments or updates to 21 C.F.R. § 1301.74; and

- DEA's guidance and/or directions given to registrants about suspicious order reports, including the scope, format, types of systems to be utilized (including automated systems), and DEA locations (field offices or headquarters) for such submissions, and how such guidance and directions changed over time.

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[1] While this Order does not expressly speak to depositions of third parties, it is the position of the United States that its agencies should not be required to provide 30(b)(6) testimony in excess of what is required of the parties to this litigation.

Mr. Thomas Prevoznik, Associate Section Chief, Pharmaceutical Investigations Section, Diversion Control Division, is authorized to provide testimony on this topic, subject to the following limitations:

First, the fourth sub-topic requests testimony on "DEA's communications with third parties…." By letter dated December 10, the Department of Justice requested that Defendants identify with specificity any "third parties," so that we could determine whether such testimony may be provided. As we have received no further clarity on the meaning of "third parties," Mr. Prevoznik is not authorized to provide testimony on the fourth sub-topic.

Second, the fifth sub-topic requests testimony on "DEA's guidance and/or directions given to registrants…." As stated in our letter dated December 10, while Mr. Prevoznik will be prepared to speak to industry-wide guidance or directions, he will not be prepared to provide testimony on communications with individual registrants over a more than 20-year time period.

Third, the fifth sub-topic requests testimony on guidance and directions from "DEA locations (field offices or headquarters)." Mr. Prevoznik will be prepared to testify regarding guidance and directions from headquarters as well as DEA's Ohio field office, which accords with the geographic limits set forth by Special Master Cohen in Discovery Ruling No. 3 (Dkt. 762). To the extent necessary and in accordance with discovery orders issued by the Court, the agency is willing to consider providing testimony on this particular sub-topic relating to other field offices at a later date.

Topic 3: Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.

- DEA's guidance to registrants relating to whether registrants are permitted to ship orders of controlled substances that the registrant determines to be "suspicious" and/or "excessive," including the nature of the purported duty to conduct due diligence, as described in the 2006 and 2007 letters from DEA to registrants, and any changes in that guidance over time;

- DEA's guidance to registrants relating to what constitutes a "suspicious order" under 21 C.F.R. § 1301.74(b), and any changes in that guidance over time;

- DEA's "Distributor Briefing" initiative, including when these briefings were given and the guidance provided to registrants relating to their obligations under the CSA;

- DEA's guidance to registrants relating to the adequacy of their suspicious order monitoring systems; and

- DEA's guidance to registrants relating to any obligation to monitor registrants' customers and the downstream supply chain.

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Mr. Prevoznik is authorized to provide testimony on this topic subject to the following limitations:

The topics and sub-topics request "guidance to registrants" on a number of subjects. As stated in our letter dated December 10, while Mr. Prevoznik will be prepared to speak to industry-wide guidance or directions, he will not be prepared to provide testimony on communications with individual registrants over a more than 20-year time period.

Topic 7: Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.

- DEA's macro-level understanding of or assessments relating to the illegal entry, distribution, or use of Prescription Opioids in the State of Ohio, including any trends that have emerged since 2006; and
- DEA's macro-level understanding of or assessments relating to the entry, distribution, or use of Illicit Opioids in the State of Ohio, including any trends that have emerged since 2006.

This topic does ***not*** encompass DEA's understanding of or investigations into individual misconduct or information that would compromise or interfere with national security.

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Based on the objection to providing testimony on this topic in our December 10 letter, Defendants offered to amend the topic to read: "Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio **where these efforts resulted from reporting of a SOR**."

The amendment does not adequately address the concern that this testimony would require DEA to reveal privileged and law enforcement sensitive information. Accordingly, no testimony is authorized on this topic.

However, by letter dated December 21, 2018, the Department of Justice is authorizing Mr. Keith Martin to provide testimony on his "personal knowledge of DEA's general efforts to combat diversion, respond to the opioid epidemic, and/or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County.." As set forth more fully in that letter, Mr. Martin is not authorized to reveal information that is privileged and/or law enforcement sensitive.

Topic 8: Inquiries or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyohoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to any registrant's filing of or failure to file Suspicious Order Reports;

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to the amount of opioid medications distributed by any registrant in the State of Ohio or in the above-listed areas;

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to the causes of the opioid epidemic;

- The total number of inquiries by government officials from the above-listed entities relating to the actual or suspected diversion of Prescription Opioids by DEA Registrants; and

- The nature, timing, and number of corrective actions taken by DEA as a result of inquiries by government officials from the above-listed entities relating to the actual or suspected diversion of Prescription Opioids by DEA Registrants.

This topic does ***not*** encompass DEA's understanding of or investigations into individual misconduct or information that would compromise or interfere with national security.

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As stated in our December 10 letter, inquiries, complaints, or communications to DEA from any Ohio county, city, township, or village that is a party to the MDL should be sought from that party and not from DEA, which is not a party to this litigation. Additionally, the testimony sought would require DEA to reveal privileged and law enforcement sensitive information. While we appreciate that the request purports not to seek "information that would compromise or interfere with national security," such a limitation is insufficient to protect privileged and law enforcement sensitive information. Furthermore, inquiries or complaints of the nature described above are not maintained in a centralized database. Consequently, this request effectively asks DEA to provide testimony on individual communications that may have occurred with an unknown number of individuals, and it would be impractical and unduly burdensome to adequately prepare a witness to provide testimony on this topic. Accordingly, no testimony is authorized on this topic.

However, by letter dated December 21, 2018, the Department of Justice is authorizing Mr. Keith Martin to provide testimony on his "personal recollection of [his] communications with any representative of Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH regarding or relating to prescription opioids." As set forth more fully in that letter, Mr. Martin is not authorized to reveal information that is privileged and/or law enforcement sensitive.

Topic 11: Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including when and why you discontinued such practice.

Mr. Prevoznik is authorized to provide testimony on this topic, subject to the following limitations:

He will not be permitted to disclose communications with counsel. Additionally, if the Defendants have specific documents on which they intend to ask questions, we request that the Defendants provide those documents at least 14 business days in advance of the scheduled deposition date so that the witness may be prepared to answer questions on those documents.

Topic 12: Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and your decisions to provide DEA-registered distributors with limited access to certain ARCOS Data in February.

Mr. Prevoznik is authorized testimony on this topic, subject to the following limitations:

For the reasons stated in our December 10, letter Mr. Prevoznik is not authorized to testify on decisions made in or after February 2018. Additionally, Mr. Prevoznik will not be permitted to disclose communications with counsel or communications that may implicate deliberative process.

Topic 13: Your practices and procedures related to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.

- DEA's procedures and practices relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids, including the factors, resources, or other information that DEA evaluates; and
- DEA personnel involved in the approval of Opioid Procurement Quotas and Opioid Production Quotas.

Topic 14: The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescriptions from 1995 to 2018.

- DEA's high-level rationale for generally and significantly increasing the Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.

This topic does ***not*** encompass individual quota decisions for particular drugs in particular years.

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Ms. Stacy Harper-Avilla Chief, UN Reporting and Quota Section, Diversion Control Division is authorized to provide testimony on these topics, subject to the following limitations:

Topics 13 and 14 seek testimony regarding "Opioid Procurement Quotas" and "Opioid Production Quotas," but DEA does not establish any quotas identified as such. Rather, DEA establishes three types of quotas for each basic class of controlled substance listed in Schedule I or II, including several basic classes of opioids. Specifically, DEA establishes an Aggregate Production Quota (APQ), which determines the total quantity of each basic class of controlled substance to be manufactured during the following calendar year. For individual manufacturers, DEA establishes individual Manufacturing Quotas (MQ) authorizing a particular registrant to

manufacture a quantity of a specific basic class of controlled substance during the next calendar year. DEA also establishes Procurement Quotas (PQ) authorizing particular registrants to procure and use quantities of each basic class of such substances for the purpose of manufacturing such class into dosage forms or into other substances.

In connection with Topic 13, therefore, DEA will provide testimony describing its practices and procedures relating to the establishment of the APQ, MQs, and PQs prior to 2018 insofar as they relate to basic classes of opioids. In connection with Topic 14, you have indicated in your letter of October 17, 2018 that "this topic does ***not*** encompass individual quota decisions for particular drugs in particular years." (emphasis in original). Thus, our understanding is that Topic 14 does not seek testimony regarding MQs and PQs, each of which encompasses only individual quota decisions. DEA will provide testimony responsive to Topic 14, as clarified in your October 17, 2018 letter, with respect to DEA's establishment of the APQ only. Please note, however, that DEA's decision to authorize testimony in response to these topics does ***not*** imply that DEA accepts the Defendants' characterization of the facts in its 30(b)(6) notice or subsequent communications about these topics.

Topic 20: The DEA's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village or city within Summit County or Cuyahoga County.

- DEA's participation in Opiate Action Team, Summit County Drug Unit, Northern Ohio Law Enforcement Task Force, Cuyahoga County Opiate Task Force, Summit County Opiate Task Force, United States Attorney's Heroin and Opioid Task Force, Ohio High Intensity Drug Trafficking Area, Summit County Drug Unit, and any other task force, organization, and/or committee with responsibilities relating to Prescription Opioids or Illicit Opioids in the state of Ohio; and

- Any assistance, included but not limited to financial grants and training, provided by DEA to the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County to investigate, respond to, or combat drug-related crimes, Prescription Opioid diversion, and/or the unlawful trafficking of Illicit Opioids.

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DEA efforts to combat diversion in these specific localities, as well as throughout the United States, are at the forefront of the agency's mission and are at the center of the day-to-day activities of the DEA's Ohio Field Office. Additionally, DEA's participation in these task forces is a matter of public record. Accordingly, no testimony is authorized on this topic. The DEA will, however, agree to provide a written response that identifies, for the task forces, units, and working groups specifically identified in the first sub-topic, whether the DEA was involved, if the DEA had a lead or supporting role, and the purpose or mission of the task force, unit, and working group.

Additionally, by letter dated December 21, 2018, the Department of Justice is authorizing Mr. Keith Martin to provide testimony on his "personal knowledge of DEA's general efforts to

combat diversion, respond to the Opioid epidemic, and/or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County." As set forth more fully in that letter, Mr. Martin is not authorized to reveal information that is privileged and/or law enforcement sensitive.

Topic 21: Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO reports:

a. ***Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (Washington, D.C.: February 2, 2015);**

b. ***Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (Washington, D.C.: June 25, 2015);**

c. ***Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations*, GAO-16-737T (Washington, D.C.: June 22, 2016).**

- The basis for DEA's representations in its response to Linda Kohn of GAO in Appendix IV of the June 25, 2015 report; and
- Actions DEA has taken to follow the recommendations of GAO in the three reports identified above.

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Ms. Donetta Spears, Diversion Program Manager, Diversion Control Division is authorized to provide testimony on this topic subject to the following limitations:

By letter dated December 10, the Department of Justice requested that Defendants identify with specificity the "actions DEA has taken to follow the recommendations of GAO in the three reports identified above." As we have received no further information from the Defendants, Ms. Spears is not authorized to provide testimony on the second sub-topic.

Topic 23: Your process for registering prescribers of controlled substances.

- The factors DEA considers in registering prescribers of controlled substances under the CSA.

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By letter dated December 10, the Department of Justice requested that Defendants provide additional clarification on what information the Defendants are seeking in light of the unambiguous statutory framework of the Controlled Substances Act and implementing regulations. As we have received no further information from the Defendants, no testimony is authorized on this topic.

Topics from Plaintiffs:

Topic 1: DEA's interpretation of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act") and its implementing regulations, including but not limited to, 21 C.F.R. Part 1300 *et seq.* (including, but not limited to, 21 C.F.R. §§ 1301.11, 1301.74), 21 C.F.R. Part 1305, and 28 C.F.R. § 0.100 with respect to a registrant's obligation to maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances," 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74, including the registrants' duty not to ship suspicious orders, and to "maintain effective controls against diversion" as described in the September 27, 2006, February 7, 2007, and December 27, 2007 letters to registrants.

Mr. Prevoznik is authorized to provide testimony on this topic

Topic 2: DEA's enforcement activities with respect to registrants who manufacture, prescribe, distribute, or dispense Opioids, including the use, disclosure, and limitations of ARCOS data.

Via telephone conference on December 17, we requested clarification on the information sought by the Plaintiffs on this topic. With respect to the type of enforcement activities that are on interest, counsel for Plaintiffs explained that Plaintiffs seek information regarding administrative actions and/or settlements that the DEA has entered into with any of the Defendants. Plaintiffs further stated that they are not seeking information on specific investigations or investigative techniques. Additionally, with respect to the information sought on the "limitations of ARCOS data," we understand that Plaintiffs are seeking information regarding how and to what extent ARCOS data may be used to further enforcement activities.

Mr. Prevoznik is authorized to provide testimony on this topic, as clarified above.

Topic 3: DEA's establishment of quotas for the production of Opioids in the United States, including aggregate production quotas, individual quotas and procurement quotas; disclosure of quota to registrants; communications with registrants regarding quota requests and the disposition of quota requests; and the relationship between quota, suspicious orders, diversion, and lawful medical, scientific, or industrial channels or use.

Ms. Harper-Avilla is authorized to provide testimony on this topic, subject to the same limitations set forth with respect to the Defendants' Topics 13 and 14 above.

Topic 4: DEA's guidance to registrants and requests for guidance from registrants with respect to any of the topics in this subpoena, including, but not limited to, all guidance and communications related to DEA's Distributor Initiative.

Ms. Spears is authorized to provide testimony on this topic, subject to the following limitations:

As stated above with respect to Defendants' Topics 2 and 3 above, while Mr. Prevoznik will be prepared to speak to industry-wide guidance or directions, he will not be prepared to provide testimony on communications with individual registrants over a more than 20-year time period. Additionally, at this time, the DEA is producing Distributor Initiative documents only insofar as they relate to the Track One Defendants.

Topic 5: DEA's interaction with the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")) regarding best practices, guidance, or enforcement related to registrants' obligations under the CSA and its implementing regulations, as laid out in Topic 1.

Mr. James Arnold , Chief DRL, Diversion Control Division, is authorized to provide testimony on this topic, subject to the following limitation:

While Mr. Arnold will be prepared to speak generally to the interactions with HDMA or HDA, he will not be prepared to provide testimony on all communications with HDMA or HDA over a more than 20-year time period.

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The above-named witnesses are not authorized to give testimony on any matter other than that which concerns the above-stated topics and information. Topics on which these witnesses are not authorized to testify include:

A. Information regarding any specific non-public DEA investigations or activities;

B. Classified and classifiable information;

C. Information that would reveal the internal deliberative process within the United States Department of Justice, including the DEA, the United States Attorney's Office, and/or any other federal departments or agencies;

D. Information that would reveal a confidential source or informant;

E. Information the disclosure of which would violate a statute, including laws governing grand jury proceedings;

F. Information that could threaten the lives or safety of any individual, including home addresses of law enforcement personnel;

G. Information that could interfere with ongoing investigations and/or prosecutions;

H. Information that could reveal investigative or intelligence gathering and dissemination techniques whose effectiveness would be thereby impaired;

I. Privileged attorney-client information;

J. Information that would reveal attorney work product or matters of prosecutorial discretion;

K. Expert opinion testimony related to non-public facts or information acquired as part of your performance of your official duties;

L. Personal opinions regarding non-public facts or information acquired as part of your performance of your official duties; and

M. Any non-public recommendations you made or you were aware of concerning any proposed agency action.

In light of the significant volume of information, including documents, testimony, and interrogatory responses, available to the parties but that has not been provided to the Department of Justice or the DEA as a non-party, the United States requests the parties to provide copies of any information that any party believes may assist the designated DEA witnesses with providing responsive, helpful testimony in the MDL and further streamlining the issues. We request that any such materials be provided as soon as possible, but no less than 14 business days before the date of the witness' deposition. Please note, however, that the witnesses offering 30(b)(6) testimony on behalf of the DEA will review and consider any such information only insofar as it is germane to the topics on which they are testifying and to the extent that the volume of information may reasonably be reviewed advance of the deposition.

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Please contact Assistant U.S. Attorney James Bennett (216-622-3988) or Senior Counsel Natalie Waites (202) 616-2964 to discuss mutually agreeable times for the deposition testimony I have authorized.

Sincerely,

AVA ROTELL DUSTIN
Executive Assistant United State Attorney
Office of the U.S. Attorney for the Northern District of Ohio
Acting Under Authority Conferred by 28 U.S.C § 515

Attachments:
(1) Letter dated October 17, 2018 from E. Mainigi to J. Bennett
(2) Letter dated December 10, 2018 from J. Bennett to E. Mainigi
(3) Letter dated December 11, 2018 from L. Singer to J. Bennett

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EDWARD BENNETT WILLIAMS (1920-1988)
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October 17, 2018

By Federal Express and Electronic Mail

James R. Bennett, Esq.
Assistant United States Attorney
Carl B. Stokes U.S. Courthouse
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Re: *Touhy* Requests in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

Dear Mr. Bennett:

I write regarding your October 2 email in which you indicated that DOJ is willing to authorize DEA to provide Rule 30(b)(6) testimony on specific topics as well as the production of documents in response to certain narrowed requests. To that end, please find below a description of the specific categories of information for each of the twelve prioritized topics identified in our September 4 letter, and a list of document custodians and search terms. We continue to discuss the other requests made in our letter of September 4.

A. 30(b)(6) Topics

2. Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

This topic encompasses the following subjects:

- DEA's policies, practices, and guidance relating to whether registrants are permitted to ship orders of controlled substances that the registrant determines to be "suspicious" and/or "excessive," including the nature of the purported duty to conduct due diligence on such orders, as described in the 2006 and 2007 letters from DEA to registrants, and any changes to those policies, practices, and guidance over time;

- DEA's interpretation of, and policies and practices relating to, what constitutes a "suspicious order" under 21 C.F.R. § 1301.74(b), and any changes thereto over time;

- DEA's interpretation of, and policies and practices relating to, registrants' obligations to "know their customers" and/or "know their customers' customers," and any changes thereto over time;

- DEA's communications with third parties concerning potential amendments or updates to 21 C.F.R. § 1301.74; and

- DEA's guidance and/or directions given to registrants about suspicious order reports, including the scope, format, types of systems to be utilized (including automated systems), and DEA locations (field offices or headquarters) for such submissions, and how such guidance and directions changed over time.

3. Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.

This topic encompasses the following subjects:

- DEA's guidance to registrants relating to whether registrants are permitted to ship orders of controlled substances that the registrant determines to be "suspicious" and/or "excessive," including the nature of the purported duty to conduct due diligence, as described in the 2006 and 2007 letters from DEA to registrants, and any changes in that guidance over time;

- DEA's guidance to registrants relating to what constitutes a "suspicious order" under 21 C.F.R. § 1301.74(b), and any changes in that guidance over time;

- DEA's "Distributor Briefing" initiative, including when these briefings were given and the guidance provided to registrants relating to their obligations under the CSA;

- DEA's guidance to registrants relating to the adequacy of their suspicious order monitoring systems; and

- DEA's guidance to registrants relating to any obligation to monitor registrants' customers and the downstream supply chain.

7. Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.

This topic encompasses the following subjects:

- DEA's macro-level understanding of or assessments relating to the illegal entry, distribution, or use of Prescription Opioids in the State of Ohio, including any trends that have emerged since 2006; and

- DEA's macro-level understanding of or assessments relating to the entry, distribution, or use of Illicit Opioids in the State of Ohio, including any trends that have emerged since 2006.

This topic does ***not*** encompass DEA's understanding of or investigations into individual misconduct or information that would compromise or interfere with national security.

8. Inquiries or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.

This topic encompasses the following subjects:

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to any registrant's filing of or failure to file Suspicious Order Reports;

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to the amount of opioid medications distributed by any registrant in the State of Ohio or in the above-listed areas;

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to the causes of the opioid epidemic;

- The total number of inquiries by government officials from the above-listed entities relating to the actual or suspected diversion of Prescription Opioids by DEA Registrants; and

- The nature, timing, and number of corrective actions taken by DEA as a result of inquiries by government officials from the above-listed entities relating to the actual or suspected diversion of Prescription Opioids by DEA Registrants.

  This topic does ***not*** encompass DEA's understanding of or investigations into individual misconduct or information that would compromise or interfere with national security.

9. Your procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS Data, Suspicious Order Reports, or other Communications from DEA Registrants to identify and stop sources of diversion.

This topic encompasses the following subjects:

- DEA's general procedures relating to the analysis of ARCOS data, Suspicious Order Reports, or other Communications from DEA Registrants identifying suspicious orders or customers from 1995 to 2014, but not including DEA's analysis of particular ARCOS data or Suspicious Order Reports.

11. Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including when and why you discontinued such practice.

12. Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and your decision to provide DEA-registered distributors with limited access to certain ARCOS Data in February 2018.

13. Your practices and procedures relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.

This topic encompasses the following subjects:

- DEA's procedures and practices relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids, including the factors, resources, or other information that DEA evaluates; and

- DEA personnel involved in the approval of Opioid Procurement Quotas and Opioid Production Quotas.

14. The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.

This topic encompasses the following subjects:

- DEA's high-level rationale for generally and significantly increasing the Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.

  This topic does ***not*** encompass individual quota decisions for particular drugs in particular years.

20. The DEA's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County.

This topic encompasses the following subjects:

- DEA's participation in Opiate Action Team, Summit County Drug Unit, Northern Ohio Law Enforcement Task Force, Cuyahoga County Opiate Task Force, Summit County Opiate Task Force, United States Attorney's Heroin and Opioid Task Force, Ohio High Intensity Drug Trafficking Area, Summit County Drug Unit, and any other task force, organization, and/or committee with responsibilities relating to Prescription Opioids or Illicit Opioids in the state of Ohio; and

- Any assistance, included but not limited to financial grants and training, provided by DEA to the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County to investigate, respond to, or combat drug-related crimes, Prescription Opioid diversion, and/or the unlawful trafficking of Illicit Opioids.

21. Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO Reports:

a. *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (Washington, D.C.: February 2, 2015);

b. *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (Washington, D.C.: June 25, 2015);

c. *Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations*, GAO-16-737T (Washington, D.C.: June 22, 2016).

This topic encompasses the following subjects:

- The basis for DEA's representations in its response to Linda Kohn of GAO in Appendix IV of the June 25, 2015 report; and

- Actions DEA has taken to follow the recommendations of GAO in the three reports identified above.

23. Your process for registering prescribers of controlled substances.

This topic encompasses the following subjects:

- The factors DEA considers in registering prescribers of controlled substances under the CSA.

B. Document Custodians and Search Terms

We propose the following document custodians:

- Demetra Ashley
- Gregory Brodersen
- Denise Foster
- Michael Mapes
- Keith Martin
- Louis Milione
- James Rafalski
- Joseph Rannazzisi
- Charles Rosenberg
- Dr. Christine Sannerud
- Alan Santos
- Matthew Strait
- Kyle Wright

Our proposed search terms are attached as **Exhibit A.**

/s/ Enu Mainigi
Enu Mainigi

Counsel for Defendant Cardinal Health, Inc.

Co-Liaison Counsel for the Distributor Defendants

/s/ Mark S. Cheffo
Mark Steven Cheffo

Counsel for Defendants Purdue Pharma L.P., Purdue Pharma Inc., and the Purdue

Frederick Company.

Co-Liaison Counsel for the Manufacturer Defendants

/s/ Shannon E. McClure
Shannon E. McClure

Counsel for Defendant AmerisourceBergen Drug Corporation.

Co-Liaison Counsel for the Distributor Defendants

/s/ Geoffrey Hobart
Geoffrey Hobart

Counsel for Defendant McKesson Corporation

Co-Liaison Counsel for the Distributor Defendants

s/ Kaspar Stoffelmayr
Kaspar Stoffelmayr

Counsel for the Walgreens Defendants.

Co-Liaison Counsel for the Chain Pharmacy Defendants

Privileged & Confidential
Attorney Work Product
Draft

DEA SEARCH TERMS

1. "§ 823" OR "Section 823" OR "S. 823" OR "S 823" OR "§823"
2. "§1301.74*" OR "1301.74*"
3. "Statutory responsibility"
4. (Suspicious w/10 order*)
5. "SOR" OR "suspicious order report"
6. "SOM"
7. "SOMS"
8. Suspicious AND (defin* OR mean* OR "what is" OR policy OR guid* OR "supply chain")
9. Algorithm*
10. Monitor* w/50 requir*
11. "controlled substance" AND report
12. Chargeback OR "charge back" OR "charge-back"
13. "Prescriber Data"
14. (ship OR halt OR report) w/25 (suspicious OR controlled)
15. ARCOS AND diver*
16. (Diver* OR abuse OR misuse) AND (opioid* OR opiate OR phentermine OR oxy* OR *codone OR hydro* OR morphine OR fent* OR carfent* OR methadone)
17. (illegal OR illicit OR foreign OR stolen) AND (opioid* OR opiate OR phentermine OR oxy* OR *codone OR hydro* OR morphine OR fent* OR carfent* OR methadone)
18. (inspect* OR audit* OR inquir* OR investigat*) AND (opioid* OR opiate OR phentermine OR oxy* OR *codone OR hydro* OR morphine OR fent* OR carfent* OR methadone)
19. "indicative of diversion"
20. "*effective controls against diversion"
21. Diligen* w/50 customer

22. customer 2/10 audit

23. (Reg* OR rule OR law OR legal) AND require* AND suspicious

24. “customer’s customer” OR “customers customer” OR “customers’ customer”

25. “Downstream customer”

26. “Downstream registrant”

27. Algorithm w/50 suspicious

28. “know your customer” OR KYC

29. “distributor initiative”

30. Letter w/10 “December 27”

31. Letter w/10 "September 27”

32. (Responsib* OR require* OR duty OR obligat*) w/25 (registrant OR suspicious OR data))

33. Report w/10 suspicious

34. “Detroit Division Office”

35. Cleveland AND “Resident Office”

36. Youngstown AND “Resident Office”

37. “Cleveland Tactical Diversion Squad”

38. “High Intensity Drug Trafficking Areas” OR “HIDTA”

39. “opioid crisis”

40. “opioid epidemic”

41. HDA OR HDMA OR “Healthcare Distribution”

42. “More DEA Information about Registrants’ Controlled Substances Role” OR “GAO-15-471”

43. “Better Management of the Quota Process for Controlled Substances Needed” OR “GAO-15-202”

44. “Additional Actions Needed to Address Prior GAO Recommendations” OR “GAO-16-737T”

45. Purdue OR Endo OR Teva OR Allergan OR Janssen OR Mallinckrodt OR Insys

46. (Diver* OR illegal OR illicit OR suspicious) AND Ohio

47. “Board of Pharmacy” AND opioid

48. (“Attorney General” OR AG) AND opioid

49. “Ohio Board of Pharmacy”

50. Cleveland AND (opioid OR opiate)

51. Akron AND (opioid OR opiate)

52. Cuyahoga AND (opioid OR opiate)

53. Summit AND (OH OR Ohio) AND

54. (opioid OR opiate)

55. Opioid w/25 (“multi-district litigation” OR “multidistrict litigation” or MDL

56. (“Washington Post” OR Higham OR Bernstein) AND opioid

57. “60 Minutes” AND

58. (opioid OR opiate)

59. opioid w/25 quota

60. “Diversion Control Fee Account” OR (diversion w/5 account”)

61. Registration AND “controlled substance” AND (opioid OR opiate)

62. (Sunrise OR Masters OR Harvard OR Cederdale) AND (audit OR suspicious OR opioid)

U.S. Department of Justice

United States Attorney
Northern District of Ohio

United States Court House
801 West Superior Avenue, Suite 400
Cleveland, Ohio 44113-1852
Main: 216-622-3600
Facsimile: 216-522-4982

December 10, 2018

Enu Mainigi
Williams and Connolly LLP
725 Twelfth Street, NW
Washington, DC 20005-5901

Re: *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio)

Dear Ms. Mainigi:

We write in response to your letter dated October 17, 2018, in which you provide a "description of the specific categories of information for each of the twelve prioritized topics identified in our September 4 letter." We understood your letter to as an offer to negotiate a narrower set of topics to address the concerns articulated in our letter dated July 25, 2018. By this letter, we are continuing to engage in a meet and confer process so that we may reach a resolution or, at a minimum, narrow the scope of the dispute before presenting the matter to one of the Special Masters.

As set forth in detail in our letter dated July 25, 2018, pursuant to 5 U.S.C. § 301, government agencies may promulgate regulations that govern how the agency will respond to third party subpoenas and requests for documents. These regulations are often known as Touhy regulations, after the Supreme Court's decision in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 467–68 (1951), in which the Court held that agency employees could not be held in contempt of court for refusing to respond to a subpoena, if instructed not to respond by a superior. In other words, once agencies have enacted these so-called Touhy regulations (and assuming the regulations are valid), government employees cannot be forced to testify. *See, e.g.*, *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003) (briefly explaining the history of Touhy and Touhy regulations). The purpose of such regulations, which typically limit the occasions on which the government will produce documents or agency employees for testimony, is "to conserve governmental resources where the United States is not a party to a suit, and to minimize governmental involvement in controversial matters unrelated to official business." *Boron Oil Co. v. Downie*, 873 F.2d 67, 70 (4th Cir. 1989). Moreover, courts are more sensitive to the discovery costs when, as here, the discovery is directed to third parties. *Watts v. SEC*, 482 F.3d 501 (D.C. Cir. 2007)).

While we appreciate the Defendants' willingness to address certain concerns raised in our July 25th letter and engage in discussions to narrow the scope of the Defendants' request for testimony under Federal Rule 30(b)(6), the 12 topics and 26 sub-topics identified in your letter remain extraordinarily broad in terms of both subject matter and time period. Moreover, your letter describes these topics as those that the Defendants wish to "prioritize," suggesting that additional Rule 30(b)(6) testimony will be requested at a later date. We cannot adequately assess the agency burden without a full understanding of the scope of the Defendants' request. To the extent that the DEA agrees to provide testimony in response to this request, Defendants must agree that they will not later seek Rule 30(b)(6) testimony on additional subjects, unless the Defendants and the United States agree in writing to such testimony. Finally, as discussed in detail below, DEA requires additional specificity with respect to certain topics to adequately prepare witnesses to testify on those topics.

Limitations for All Topics:

First, it is our position that any 30(b)(6) testimony authorized on the specific topics indicated below should be limited to the time period between January 1, 2004 and December 31, 2015. Second, a number of the topics request testimony relating to "controlled substances." Any authorized testimony should be limited solely to opioids that meet the definition of controlled substances.

Specific Topics:

Topic 2: Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

We anticipate that the Department would authorize testimony on this topic, including the sub-topics indicated in your October 17 letter, with the following limitations:

First, the fourth sub-topic requests testimony on "DEA's communications with third parties…." Please identify with specificity any "third parties," so that we can determine whether such testimony may be provided.

Second, the fifth sub-topic requests testimony on "DEA's guidance and/or directions given to registrants…." While the agency's witness on this topic will be prepared to speak to industry-wide guidance or directions, it is impractical to prepare the witness to provide testimony on communications with individual registrants over a more than 10-year time period.

Third, the fifth sub-topic requests testimony on guidance and directions from "DEA locations (field offices or headquarters)." The agency's witness will be prepared to testify regarding guidance and directions from headquarters as well as DEA's Ohio field office, which accords with the geographic limits set forth by Special Master Cohen in Discovery Ruling No. 3 (Dkt. 762). To the extent necessary and in accordance with discovery orders issued by the Court, the agency is willing to consider providing testimony on this particular sub-topic relating to other field offices at a later date.

Topic 3: Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.

We anticipate that the Department would authorize testimony on this topic, including the sub-topics indicated in your October 17 letter, with the following limitations:

The topics and sub-topics request "guidance to registrants" on a number of subjects. While the agency's witness on this topic will be prepared to speak to industry-wide guidance or directions, it is impractical to prepare the witness to provide testimony on communications with individual registrants over a more than 10-year time period.

Topic 7: Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.

DEA objects to this topic. As an initial matter, the information sought appears to lack relevance – or has only the most attenuated connection to the issues being litigated in the MDL – and accordingly, the burden of providing such testimony would significantly outweigh the benefit. Additionally, the testimony sought would require DEA to reveal privileged and law enforcement sensitive information. This topic is also duplicative and cumulative with topic 20 which seeks much of the same information.

Topic 8: Inquires or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyohoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.

DEA objects to this topic. As an initial matter, inquiries, complaints, or communications to DEA from any Ohio county, city, township, or village that is a party to the MDL should be sought from that party and not from DEA, which is a third party in this litigation. Additionally, the testimony sought would require DEA to reveal privileged and law enforcement sensitive information. While we appreciate that the request purports not to seek "information that would compromise or interfere with national security," such a limitation is insufficient to protect privileged and law enforcement sensitive information. Furthermore, inquiries or complaints of the nature described above are not maintained in a centralized database. Consequently, this request effectively asks DEA to provide testimony on individual communications that may have occurred with an unknown number of individuals, and it would be impractical to seek to adequately prepare a witness to provide testimony on this topic.

Topic 11: Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including when and why you discontinued such practice.

We anticipate that the Department would authorize testimony on this topic with the following limitations:

The witness will not be permitted to disclose communications with counsel. Additionally, if the Defendants have specific documents on which they intend to ask questions, we request that the Defendants provide those documents at least fourteen business days in advance of the scheduled deposition date so that the witness may be prepared to answer questions on those documents.

Topic 12: Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and your decisions to provide DEA-registered distributors with limited access to certain ARCOS Data in February.

We anticipate that the Department would authorize testimony on this topic with the following limitations:

As an initial matter, as of February 2018, DEA announced that it would be providing access to certain aggregated data, not de-identified data, which suggests that the topic is based on a misunderstanding of DEA's position. Consequently, we request that the Defendants clarify this topic. Furthermore, we do not think that the DEA's decision in February 2018 is relevant to the litigation in the MDL, and we object to providing any testimony on decisions made in or after February 2018.

Additionally, the witness will not be permitted to disclose communications with counsel or communications that may implicate deliberative process.

Topic 13: Your practices and procedures related to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.

We anticipate that the Department would authorize testimony on this topic, including the sub-topics indicated in your October 17 letter, subject to the general limitations set forth above with respect to all topics.

Topic 14: The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescriptions from 1995 to 2018.

We anticipate that the Department would authorize testimony on this topic, including the sub-topics indicated in your October 17 letter, subject to the general limitations set forth above with respect to all topics.

Topic 20: The DEA's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village or city within Summit County or Cuyahoga County.

This topic is duplicative and cumulative with topic 7, which seeks much of the same information.

We anticipate that the Department would authorize testimony on this topic, including the sub-topics indicated in your October 17 letter, with the following limitation:

DEA will not provide testimony that would reveal privileged and law enforcement sensitive information.

Topic 21: Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO reports [listing GAO reports dated February 2, 2015; June 25, 2015; and June 22, 2016].

We anticipate that the Department would authorize testimony on this topic, including the sub-topics indicated in your October 17 letter, with the following limitations:

We anticipate that the Department would authorize non-privileged testimony on "the basis for DEA's representations in its response to Linda Kohn of GAO in Appendix IV of the June 25, 2015 report."

With respect to the request for testimony regarding "actions DEA has taken to follow the recommendations of GAO in the three reports identified above," this request lacks specificity and, as drafted, appears to have limited, if any, relevance to the issues being litigated in the MDL. Accordingly, the burden of providing such testimony would significantly outweigh the benefit. If Defendants can provide more specificity on the information sought, DEA will consider that information.

Topic 23: Your process for registering prescribers of controlled substances.

The Controlled Substances Act, 21 U.S.C. § 823(b), provides that "[t]he Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest." The statute then sets forth the factors that are considered in determining the public interest. *See also* 21 C.F.R. § 1301.35(a)("The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of sections 303 or 1008 of the Act (21 U.S.C. 823 and 958)".) In light of this unambiguous statutory framework, it is unclear what additional information is sought by the Defendants. Accordingly, DEA seeks additional clarification from Defendants on the testimony sought.

*****

We look forward to working with you to resolve remaining questions regarding the Defendants' requests and to schedule deposition dates as expeditiously as possible.

Sincerely,

AVA ROTELL DUSTIN
Executive Assistant United States Attorney
Office of the United States Attorney
Northern District of Ohio
Acting Under Authority Conferred by 28 U.S.C. § 515

By: */s/James R. Bennett II*
JAMES R. BENNETT II
Assistant U.S. Attorney
NATALIE A. WAITES
Senior Counsel
Commercial Litigation Branch
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I am a trial lawyer."
–Ron Motley (1944–2013)

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Linda Singer
Licensed in DC, NY
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lsinger@motleyrice.com

December 11, 2018

By Federal Express and Electronic Mail

Mr. James R. Bennett II
Assistant U.S. Attorney
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue, Suite 400
Cleveland, Ohio 44113-1853
E-mail: James.Bennett4@usdoj.gov
Attorney for the United States Department of Justice,
Drug Enforcement Administration

Re: Subpoena in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

Dear Mr. Bennett:

I write on behalf of the bellwether plaintiffs in the matter of *In re National Prescription Opiate Litigation,* MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find a copy of a federal subpoena for witness testimony calling for the appearance of a Federal Rule of Civil Procedure 30(b)(6) witness or witnesses at a deposition. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance by directing this letter to you. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 386-9626, or lsinger@motleyrice.com, if you have questions concerning this subpoena or require additional information.

Sincerely,

/s/ Linda Singer

Linda Singer

GOVERNMENT EXHIBIT
Letter 3

MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-386-9626
Fax: 202-386-9622
lsinger@motleyrice.com
Counsel for County of Summit, Ohio and City of Akron, Ohio

Cc (via e-mail):
Alexander K. Haas, Special Counsel to the Assistant Attorney General, Civil Division

AO 88A (Rev. 02/14) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re: National Prescription Opiate Litig.

Plaintiff

v.

Defendant

Civil Action No. 17-md-2804

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: United States Drug Enforcement Administration, P.O. Box 2639, Springfield, VA 22152-2639

(Name of person to whom this subpoena is directed)

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Please see attached Notice of Deposition.

Place:	Date and Time:
Motley Rice LLC 401 9th St. N.W., Suite 1001, Washington D.C. 20004	01/15/2018 10:00 am

The deposition will be recorded by this method: Stenographic and/or by video and audio recording

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

Please see attached Notice of Deposition.

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 12/11/2018

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Linda Singer

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* County of Summit and City of Akron, Ohio, who issues or requests this subpoena, are:

Linda Singer, Motley Rice LLC, 401 9th St. N.W., Suite 1001, Washington D.C. 20004, (202)232-5504, lsinger@motleyrice.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 17-md-2804

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Print Save As... Add Attachment Reset

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 1:18-OP-45090 (N.D. Ohio) *City of Cleveland v. Purdue Pharma L.P., et al.*, Case No. 18-OP-45132 (N.D. Ohio); *The County of Cuyahoga v. Purdue Pharma L.P., et al.*, Case No. 17-OP-45004 (N.D. Ohio).	MDL NO. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

TRACK ONE PLAINTIFFS' NOTICE OF DEPOSITION

PLEASE TAKE NOTICE that, pursuant to Federal Rule of Civil Procedure 30(b)(6), you are required to designate the most knowledgeable person(s) to fully describe the matters set forth in Exhibit 1 attached hereto. Please take further notice that the witness is required to produce for inspection and copying at the time and place noticed above, all documents and tangible things specified in Exhibit 2 attached hereto.

The deposition(s) of the most knowledgeable person(s) shall take place at the date and time set forth below:

Deponent:	Rule 30(b)(6) via Designated Corporate Representative(s) of United States Drug Enforcement Administration ("DEA") (please see attached Exhibit 1).
Date:	January 15, 2018, commencing at 10 a.m. local time.
Place:	Motley Rice LLC 401 9th St. N.W., Suite 1001 Washington, DC 20004

The deposition will be recorded stenographically, by video, and through instant visual display of testimony by means of LiveNote or other similar technology, before a notary public or other person authorized to administer oaths pursuant to Federal Rule of Civil Procedure 28(a). The deposition will continue from day to day until completed, weekends and Court-recognized holidays excepted.

Plaintiff requests that DEA produce at each deposition a copy of the designated representative's current curriculum vitae or résumé.

Duty to Designate

By designating a representative, DEA indicates its representative has authority to speak on its behalf on the matters listed in this notice – not only to facts, but also to subject beliefs and opinions.

Duty to Substitute

If it becomes clear that the chosen representative is unable to respond to questions on the matters for which he or she has been designated, DEA must immediately provide a substitute knowledgeable witness. This is required even if the initial designation was made in good faith.

You are invited to attend and take part as is fit and proper.

Dated: December 11, 2018,

/s/ *Linda Singer*

Linda Singer
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-232-5504
Fax: 202-386-9622
lsinger@motleyrice.com
Counsel for County of Summit, Ohio and City of Akron, Ohio

EXHIBIT 1

The United States Drug Enforcement Administration ("DEA") is required by this notice and Rule 30(b)(6) to designate one or more directors, officers, managing agents or other persons who are most knowledgeable to testify on its behalf as to all matters known or reasonably available to DEA concerning the following matters. For each person identified, DEA shall identify the matters on which the designee will testify.

I. DEFINITIONS

This section sets forth specific definitions applicable to certain words and terms used herein. Unless words or terms have been given a specific definition in this section or in a specific request, each word or term shall be given its usual and customary dictionary definition, except where a word or term has a specific customary and usage definition in your trade and industry. In that case, the word or term shall be interpreted in accordance with the specific customary and usage definition.

1. "Action" or "MDL" refers to *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP) (N.D. Ohio).

2. "Complaint(s)" means the most recently filed complaint(s) in this the County of Summit, Ohio, the City of Akron, Ohio, the County of Cuyahoga, Ohio, and the City of Cleveland Ohio, in the three "Track One" cases in MDL 2804: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, No. 18-op-45090; *The County of Cuyahoga, Ohio et al. v. Purdue Pharma L.P., et al.*, No. 18-op-40004; and, *the City of Cleveland, Ohio v. Purdue Pharma L.P., et al.*, No. 18-op-45132.

3. "Controlled Substance(s)" has the definition provided by the CSA (defined below), 21 U.S.C. §802(6).

4. "CSA" means Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801, *et seq.*, inclusive of all regulations adopted thereunder.

5. "DEA" means Drug Enforcement Administration.

6. "Diversion" means the unlawful channeling of a licit Controlled Substance for an illicit purpose or use.

7. "Opioid" refers to that class of drugs, legal or illegal, natural or synthetic, used to control pain, including, but not limited to, the drugs referenced in the Complaint in the above-referenced matter.

8. Any capitalized terms used but not defined herein shall have the same meaning assigned to them in the Complaint if any such meaning was provided therein.

9. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the 30(b)(6) topic all subject matters that might otherwise be construed to be outside of its scope.

II. RELEVANT TIME PERIOD

Except as otherwise specified, the Relevant Time Period applicable to the Subject Matters for Testimony is 1996 to the present, inclusive.

III. SUBJECT MATTERS FOR TESTIMONY

In accordance with Federal Rule of Civil Procedure 30(b)(6), the following designated matters identify topics upon which examination is requested and the minimum to which a witness must be prepared to testify. If an examining party asks questions outside the scope of the matters described in the notice, general deposition rules govern.

1. DEA's interpretation of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act") and its implementing regulations, including but not limited to, 21 C.F.R. Part 1300 *et seq.* (including, but not limited to, 21 C.F.R. §§ 1301.11, 1301.74), 21 C.F.R. Part 1305, and 28 C.F.R. § 0.100 with respect to a registrant's obligation to maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances," 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74, including the registrants' duty not to ship suspicious orders, and to "maintain effective controls against diversion" as described in the September 27, 2006, February 7, 2007, and December 27, 2007 letters to registrants.

2. DEA's enforcement activities with respect to registrants who manufacture, prescribe, distribute, or dispense Opioids, including the use, disclosure, and limitations of ARCOS data.

3. DEA's establishment of quotas for the for the production of Opioids in the United States, including aggregate production quotas, individual quotas and procurement quotas; disclosure of quota to registrants; communications with registrants regarding quota requests and the disposition of quota requests; and the relationship between quota, suspicious orders, diversion, and lawful medical, scientific, or industrial channels or use.

4. DEA's guidance to registrants and requests for guidance from registrants with respect to any of the topics in this subpoena, including, but not limited to, all guidance and communications related to DEA's Distributor Initiative.

5. DEA's interaction with the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")) regarding best practices, guidance, or enforcement related to registrants' obligations under the CSA and its implementing regulations, as laid out in Topic 1.

EXHIBIT 2

Pursuant to Federal Rule of Civil Procedure 30(b)(2) and 34, the deponent should produce all documents relied upon by the representative(s) in preparing for the testimony identified in Exhibit 1. Order on Discovery in Track One Cases and Amending Prior Orders, §IV ¶3, *In re: National Prescription Opiate Litigation* (N.D. Ohio 17-md-2804).

CERTIFICATE OF SERVICE

I hereby certify that because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance by directing a letter through the Assistant United States Attorney.

/s/ *Linda Singer*

Linda Singer
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-232-5504
Fax: 202-386-9622
lsinger@motleyrice.com
Counsel for County of Summit, Ohio and City of Akron, Ohio

This 11th day of December, 2018

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***All Cases***	**Case No.: 1:17-md-2804-DAP** **Honorable Dan Aaron Polster**

CASE MANAGEMENT ORDER NO. 2: PROTECTIVE ORDER

I. Scope of Order

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order ("Protective Order" or "Order"). Unless otherwise noted, this Order is also subject to the Local Rules of this District and the Federal Rules of Civil Procedure on matters of procedure and calculation of time periods. Unless otherwise stated, all periods of time provided for in this Order are calculated as calendar days

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, captioned as *In re: National Prescription Opiate Litigation* (MDL No. 2804), Case No. 1:17-CV-2804, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there ("the Litigation"). All materials produced or adduced in the course of

discovery, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this Litigation (the "Producing Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon all the Parties to this Litigation, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

II. Definitions

7. Party. "Party" means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential

Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. "Discovery Material" means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation.

9. Competitor. Competitor means any company or individual, other than the Designating Party, engaged in the design; development; manufacture; regulatory review process; dispensing; marketing; distribution; creation, prosecution, pursuit, or other development of an interest in protecting intellectual property; and/or licensing of any product or services involving opioids; provided, however, that this section shall not be construed as limiting the disclosure of Discovery Material to an Expert in this Litigation, so long as the notice required under Paragraph 38 is provided to the Designating Party prior to any such disclosure where required, and so long as no Discovery Material produced by one Defendant is shown to any current employee or consultant of a different Defendant,

except as provided in Paragraphs 33 or 34.

10. Confidential Information. "Confidential Information" is defined herein as information that the Producing Party in good faith believes would be entitled to protection on a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) on the basis that it constitutes, reflects, discloses, or contains information protected from disclosure by statute or that should be protected from disclosure as confidential personal information, medical or psychiatric information, personnel records, Confidential Protected Health Information, protected law enforcement materials (including investigative files, overdose records, narcane, coroner's records, court records, and prosecution files), research, technical, commercial or financial information that the Designating Party has maintained as confidential, or such other proprietary or sensitive business and commercial information that is not publicly available. Public records and other information or documents that are publicly available may not be designated as Confidential Information. In designating discovery materials as Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Confidential."

11. Highly Confidential Information. "Highly Confidential Information" is defined herein as information which, if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not enumerated in Paragraphs 32 and 33, could reasonably result in possible antitrust violations or commercial, financial, or business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective

Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as "Highly Confidential."

12. Manufacturer Defendant: Manufacturer Defendant means any Defendant in this litigation that manufactures any Opioid Product for sale or distribution in the United States.

13. Distributor Defendant: Distributor Defendant means any Defendant in this litigation that distributes any Opioid Product in the United States other than a product they manufacture or license for manufacture.

14. Retail Defendant: Retail Defendant means any Defendant in this litigation that sells or distributes any Opioid Product directly to consumers in the United States.

15. Receiving Party. "Receiving Party" means a Party to this Litigation, and all employees, agents, and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

16. Producing Party. "Producing Party" means a Party to this Litigation, and all directors, employees, and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

17. Protected Material. "Protected Material" means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as "Confidential" or "Highly Confidential" in accordance with this Protective Order.

18. Outside Counsel. "Outside Counsel" means any law firm or attorney who

represents any Party for purposes of this litigation.

19. In-House Counsel. "In-House Counsel" means attorney employees of any Party.

20. Counsel. "Counsel," without another qualifier, means Outside Counsel and In- House Counsel.

21. Independent Expert. "Independent Expert" means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their staff who are not employed by a Party to whom it is reasonably necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

22. This Litigation. "This Litigation" means all actions in MDL No. 2804, *In re: National Prescription Opiate Litigation* or hereafter subject to transfer to MDL No. 2804.

III. Designation and Redaction of Confidential Information

23. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

24. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation "CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER", or "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" or comparable notices.

25. Information disclosed through testimony at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party's receipt of the certified transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or Highly Confidential Information and the "HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed.

26. In accordance with this Protective Order, only the persons identified under Paragraphs 33 and 34, below, along with the witness and the witness's counsel may be present if any questions regarding Confidential Information or Highly Confidential are asked. This paragraph shall not be deemed to authorize disclosure of any document or information to any person to whom disclosure is prohibited under this Protective Order.

27. A Party in this Litigation may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" any document, material, or other information produced by, or testimony given by, any other person or entity that the designating Party reasonably believes

qualifies as the designating Party's Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

28. This Protective Order shall not be construed to protect from production or to permit the "Confidential Information" or "Highly Confidential Information" designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party or the individual or individuals who caused the information to become public, generally available to the public through publication or otherwise.

29. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, a Producing Party may redact certain Confidential or Highly Information from produced documents, materials or other things. The basis for any such redaction shall be stated in the Redaction field of the metadata produced pursuant to the Document Production Protocol or, in the event that such metadata is not technologically feasible, a log of the redactions. Specifically, the Producing Party may redact:

(i) Personal Identifying Information. The names, home addresses, personal email addresses, home telephone numbers, Social Security or tax identification numbers, and other private information protected by law of (a) current and former employees (other than employees' names and business contact information) and (b) individuals in clinical studies or adverse event reports whose identity is protected by law.

(ii) Privileged Information. Information protected from disclosure by the attorney-client privilege, work product doctrine, or other such legal privilege protecting information from discovery in this Litigation. The obligation to provide, and form of, privilege logs will be addressed by separate Order.

(iii) Third Party Confidential Information. If agreed to by the Parties or ordered by the Court under Paragraph 78, information that is protected pursuant to confidentiality agreements between Designating Parties and third parties, as long as the agreements require Designating Parties to redact such information in order to produce such documents in litigation.

30. To the extent any document, materials, or other things produced contain segregated, non-responsive Confidential or Highly Confidential Information concerning a Producing Party's non-opioid products (or, in the case of Plaintiffs, concerning programs, services, or agencies not at issue in this litigation), the Producing Party may redact that segregated, non-responsive, Confidential or Highly Confidential information except (a) that if a Producing Party's non-opioid product is mentioned in direct comparison to the Producing Party's opioid product, then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the Producing Party's non-opioid product(s) would render the information pertaining to Producing Party's opioid product meaningless or would remove the context of the information about

Producing Party's opioid product, the name and information about the other product may not be redacted. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

31. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients who were reported as experiencing adverse events that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

IV. Access to Confidential and Highly Confidential Information

32. General. The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential or Highly Confidential Information to any third person or entity except as set forth in Paragraphs 33 and 34.

33. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 33.l) and its contents shall not be disclosed to any person unless that person falls within at least one of the following categories:

a. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;

b. Vendor agents retained by the parties or counsel for the parties, provided

that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

c. Individual Parties;

d. Present or former officers, directors, and employees of a Party, provided that former officers, directors, or employees of the Designating Party may be shown documents prepared after the date of his or her departure only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Litigation and provided that such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Nothing in this paragraph shall be deemed to permit the showing of one defendant's Confidential Information to an officer, director, or employee of another defendant, except to the extent otherwise authorized by this Order;

e. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;

f. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

g. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

h. Any individual(s) who authored, prepared, or previously reviewed or received the information;

i. To the extent contemplated by Case Management Order One, dated April 11, 2018 (Dkt. No. 232), those liability insurance companies from which any Defendant has sought or may seek insurance coverage to (i) provide or reimburse for the defense of the Litigation and/or (ii) satisfy all or part of any liability in the Litigation.

j. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.

k. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;

l. Counsel for claimants in litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient agrees to be bound by this Protective Order and completed the certification

contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant, provided, however, that any such recipient of documents or information produced under this Order shall submit to the jurisdiction of this Court for any violations of this Order.; or

m. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

34. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 34.j) and its contents shall not be disclosed to any person unless

that person falls within at least one of the following categories:

a. Outside Counsel and In-House Counsel of any Plaintiff, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. Information designated as Highly Confidential by any Defendant may be disclosed to one In-House counsel of another Defendant, provided that the In-House counsel (i) has regular involvement in the Litigation, (ii) disclosure to the individual is reasonably necessary to this Litigation, and (iii) the individual completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Except as otherwise provided in this Order or any other Order in this Litigation, no other Employees of a Defendant may receive the Highly Confidential information of another. Any information designated as Highly Confidential shall be disclosed to an In-House Counsel for any Plaintiff only to the extent Outside Counsel for that Plaintiff determines in good faith that disclosure to the In-House Counsel is reasonably necessary to the Litigation;

b. Vendor agents retained by the parties or counsel for the parties, provided that the vendor agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;;

c. Individual Parties that have produced the designated information;

d. Stenographic employees and court reporters recording or transcribing testimony in this Litigation;

e. The Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

f. Formally retained independent experts and/or consultants, provided that the recipient agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound;

g. Any individual(s) who authored, prepared or previously reviewed or received the information;

h. State or federal law enforcement agencies, but only after such persons have completed the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Disclosure pursuant to this subparagraph will be made only after the Designating Party has been given ten (10) days' notice of the Receiving Party's intent to disclose, and a description of the materials the Receiving Party intends to disclose. If the Designating Party objects to disclosure, the Designating Party may request a meet and confer and may seek a protective order from the Court.

i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 2804 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order;

j. Counsel for claimants litigation pending outside this Litigation and arising from one or more Defendants' manufacture, marketing, sale, or distribution of opioid products for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient

agrees to be bound by this Protective Order and completes the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound. Plaintiffs' Liaison Counsel shall disclose to all Defendants at the end of each month a cumulative list providing the identity of the counsel who have executed such acknowledgements and will receive Confidential and Highly Confidential Information pursuant to this Order and a list of the case name(s), number(s), and jurisdiction(s) in which that counsel represents other claimants. Neither the receipt of information pursuant to this paragraph nor the provision of the certification shall in any way be deemed a submission, by the claimant represented by counsel in such outside litigation, to the jurisdiction of this Court or any other federal court or a waiver of any jurisdictional arguments available to such claimant; or

k. Witnesses during deposition, who may be shown, but shall not be permitted to retain, Highly Confidential Information; provided, however, that, unless otherwise agreed by the relevant Parties or ordered by the Court, no Highly Confidential Information of one defendant may be shown to any witness who is a current employee of another defendant who is not otherwise authorized to receive the information under this Order.

35. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated "CONFIDENTIAL," except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel (or current employees) of any Competitor of the Producing Party, except as otherwise provided in this Order or any other Order in this Litigation.

36. In the event that In-House Counsel (or current employees) of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document designated as Highly Confidential being used in the examination, such In-House Counsel (current employees) of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

V. Confidentiality Acknowledgment

37. Each person required under this Order to complete the certification contained in Exhibit A, Acknowledgment and Agreement to Be Bound, shall be provided with a copy of this Protective Order, which he or she shall read, and, upon reading this Protective Order, shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Unless otherwise provided in this Order, Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The Parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements, but must comply with the terms of this Protective Order.

VI. Litigation Experts and Consultants.

38. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to Paragraph 37 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party in connection with a Competitor's opioid product. Prior to the initial disclosure of any information designated as Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party in connection with a Competitor's opioid product, the party wishing to make such a disclosure ("Notifying Party") shall provide to counsel for the Producing Party in writing, which may include by e- mail, a statement that such disclosure will be made, identifying the general subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the general purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have seven (7) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections (if any), which may include e-mail, to such disclosure to the expert or consultant.

39. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order. Upon and pending resolution of a timely objection, disclosure to the expert or

consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after seven (7) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless within that seven day period, the Producing Party seeks relief from the Court pursuant to the procedures for discovery disputes set forth in Section 9(o) of Case Management Order One, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

VII. Protection and Use of Confidential and Highly Confidential Information

40. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

41. Nothing herein shall restrict a person qualified to receive Confidential

Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

42. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 46. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

43. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel

shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

44. Nothing contained in this Protective Order shall prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Protective Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing

45. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

46. To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

47. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

48. Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal of this Litigation.

49. Within ninety (90) days after dismissal or entry of final judgment not subject to further appeal of this Litigation, or such other time as the Producing Party may agree in writing, the Receiving Party shall return all Confidential Information and Highly Confidential Information under this Protective Order unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return;[1] or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

50. Notwithstanding the above requirements to return or destroy documents, Plaintiffs' outside counsel and Defendants' outside counsel may retain (1) any materials required to be retained by law or ethical rules, (2) one copy of their work file and work product, and (3) one complete set of all documents filed with the Court including those filed under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential Discovery Material shall continue to be protected under this Protective Order. An attorney may use his or her work product in subsequent litigation, provided that the attorney's use does not disclose or use Confidential Information or Highly Confidential Information.

[1] The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information or Highly Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails (including attachments to e-mails) that may include Confidential Information or Highly Confidential Information, or Confidential Information or Highly Confidential Information contained in deposition transcripts or drafts or final expert reports.

VIII. Changes in Designation of Information

51. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order, and provide replacement media, images, and any associated production information to conform the document to the appropriate designation and facilitate use of the revised designation in the production. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" or withdraw a "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description, along with the replacement media, images, and associated production information referenced above. Upon receipt of any redesignation and replacement image that designates material as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL", the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this

Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party's good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

52. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. If the Receiving Party believes that portion(s) of a document are not properly designated as Confidential Information or Highly Confidential Information, the Receiving Party will identify the specific information that it believes is improperly designated and notify the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within seven (7) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, it shall notify the Producing Party and the Receiving Party shall have seven (7) days from such notification to challenge the designation by commencing a discovery dispute under the procedures set forth in Section 9(o) of Case Management Order One. The ultimate burden of persuasion in any such challenge proceeding shall be on the Producing Party as if the Producing Party were seeking a Protective Order pursuant to Fed. R. Civ. P. 26(c) in the first instance. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation. In the even that a designation is changed by the Producing Party or by Court Order, the Producing Party shall provide replacement media,

images, and associated production information as provided above.

IX. Inadvertent Production of Documents

53. Non-Waiver of Privilege. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure ("Privileged Information"). If, nevertheless, a Producing Party discloses Privileged Information, such disclosure (as distinct from use) shall be deemed inadvertent without need of further showing under Federal Rule of Evidence 502(b) and shall not constitute or be deemed a waiver or forfeiture of the privilege or protection from discovery in this case or in any other federal or state proceeding by that party (the "Disclosing Party"). This Section shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

54. Notice of Production of Privileged Information. If a Party or non-Party discovers that it has produced Privileged Information, it shall promptly notify the Receiving Party of the production in writing, shall identify the produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Designating Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Designating Party in writing that the Receiving Party possesses potentially Privileged Information. The Designating Party shall have seven (7) days to assert privilege over the identified information. If the Designating Party does not assert a claim of privilege within the 7-day period, the information in question shall be deemed non-privileged.

55. Recall of Privileged Information. If the Designating Party has notified the Receiving Party of production, or has confirmed the production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the produced Privileged Information requested to be returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the produced Privileged Information; and (3) ensure that produced Privileged Information is not disclosed in any manner to any Party or non-Party. The following procedures shall be followed to ensure all copies of such ESI are appropriately removed from the Receiving Party's system:

i. Locate each recalled document in the document review/production database and delete the record from the database;

ii. If there is a native file link to the recalled document, remove the native file from the network path;

iii. If the database has an image load file, locate the document image(s) loaded into the viewing software and delete the image file(s) corresponding to the recalled documents. Remove the line(s) corresponding to the document image(s) from the image load file;

iv. Apply the same process to any additional copies of the document or database, where possible;

v. Locate and destroy all other copies of the document, whether in electronic or hardcopy form. To the extent that copies of the document are contained on write-protected media, such as CDs or DVDs, these media shall be discarded, with the exception of production media received from the recalling party, which shall be treated as

described herein;

vi. If the document was produced in a write-protected format, the party seeking to recall the document shall, at its election, either (i) provide a replacement copy of the relevant production from which the document has been removed, in which case the receiving party shall discard the original production media; or (ii) allow the receiving party to retain the original production media, in which case the receiving party shall take steps to ensure that the recalled document will not be used; and

vii. Confirm that the recall of ESI under this procedure is complete by way of letter to the party seeking to recall ESI.

56. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any produced Privileged Information in connection with this Litigation or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Designating Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege.

57. Within 14 days of the notification that such Privileged Information has been returned, destroyed, sequestered, or deleted ("Clawed-Back Information"), the Disclosing Party shall produce a privilege log with respect to the Clawed-Back Information. Within 14 days after receiving the Disclosing Party's privilege log with respect to such Clawed-Back Information, a receiving party may notify the Disclosing Party in writing of an objection to a claim of privilege or work-product protection with respect to the Clawed-Back Information. Within 14 days of the receipt of such notification, the Disclosing Party

and the objecting party shall meet and confer in an effort to resolve any disagreement concerning the Disclosing Party's privilege or work-product claim with respect to such Clawed-Back Information. The parties may stipulate to extend the time periods set forth in this paragraph.

58. If, for any reason, the Disclosing Party and Receiving Party (or parties) do not resolve their disagreement after conducting the mandatory meet and confer, the Receiving Party may request a conference with the Court pursuant to the procedures set forth in Case Management Order One. The Disclosing Party bears the burden of establishing the privileged or protected nature of any Privileged Information.

59. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. Nothing in this Order shall limit the right to request an in-camera review of any Privileged Information.

60. In the event any prior order or agreement between the parties and/or between the parties and a non-party concerning the disclosure of privileged and/or work product protected materials conflicts with any of the provisions of this Order, the provisions of this Stipulated Order shall control.

61. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced.

X. Filing and Use at Trial of Protected Material

62. Only Confidential or Highly Confidential portions of relevant documents

are subject to sealing. To the extent that a brief, memorandum, or pleading references any document designated as Confidential or Highly Confidential, then the brief, memorandum or pleading shall refer the Court to the particular exhibit filed under seal without disclosing the contents of any confidential information. If, however, the confidential information must be intertwined within the text of the document, a party may timely move the Court for leave to file both a redacted version for the public docket and an unredacted version for sealing.

63. Absent a Court-granted exception based upon extraordinary circumstances, any and all filings made under seal shall be submitted electronically and shall be linked to this Stipulated Protective Order or other relevant authorizing order. If both redacted and unredacted versions are being submitted for filing, each version shall be clearly named so there is no confusion as to why there are two entries on the docket for the same filing.

64. If the Court has granted an exception to electronic filing, a sealed filing shall be placed in a sealed envelope marked "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The sealed envelope shall display the case name and number, a designation as to what the document is, the name of the party on whose behalf it is submitted, and the name of the attorney who has filed the sealed document. A copy of this Stipulated Protective Order, or other relevant authorizing order, shall be included in the sealed envelope.

65. A Party that intends to present Confidential Information or Highly Confidential Information at a hearing shall bring that issue to the Court's and Parties' attention without disclosing the Confidential Information or Highly Confidential Information. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential Information

at the hearing. The use of any Confidential Information or Highly Confidential Information at trial shall be governed by a separate stipulation and/or court order.

XI. Information or Highly Confidential Information Requested by Third Party; Procedure Following Request.

66. If any person receiving Discovery Material covered by this Protective Order (the "Receiver") is served with a subpoena, a request for information, or any other form of legal process that purports to compel disclosure of any Confidential Information or Highly Confidential Information covered by this Protective Order ("Request"), the Receiver must so notify the Designating Party, in writing, immediately and in no event more than five (5) court days after receiving the Request. Such notification must include a copy of the Request.

67. The Receiver also must immediately inform the party who made the Request ("Requesting Party") in writing that some or all the requested material is the subject of this Protective Order. In addition, the Receiver must deliver a copy of this Protective Order promptly to the Requesting Party.

68. The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to protect its Confidential Information or Highly Confidential Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Litigation to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Receiver has in its possession, custody or control Confidential Information or Highly Confidential Information by the other Party in this Litigation.

69. Materials that have been designated as Confidential or Highly Confidential Discovery Material shall not be provided or disclosed to any third party in response to a request under any public records act, or any similar federal, state or municipal law (collectively, the "Public Disclosure Laws"), and are exempt from disclosure pursuant to this Protective Order. If a Party to this Litigation receives such a request, it shall (i) provide a copy of this Protective Order to the Requesting Party and inform it that the requested materials are exempt from disclosure and that the Party is barred by this Protective Order from disclosing them, and (ii) promptly inform the Designating Party that has produced the requested material that the request has been made, identifying the name of the Requesting Party and the particular materials sought. If the Designating Party seeks a protective order, the Receiving Party shall not disclose such material until the Court has ruled on the request for a protective order. The restrictions in this paragraph shall not apply to materials that (i) the Designating Party expressly consents in writing to disclosure; or (ii) this Court has determined by court order to have been improperly designated as Confidential or Highly Confidential Discovery Material. The provisions of this section shall apply to any entity in receipt of Confidential or Highly Confidential Discovery Material governed by this Protective Order. Nothing in this Protective Order shall be deemed to (1) foreclose any Party from arguing that Discovery Material is not a public record for purposes of the Public Disclosure Laws; (2) prevent any Party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a Party may make as to why Discovery Material is exempt from disclosure.

XII.HIPAA-Protected Information

70. General. Discovery in this Litigation may involve production of "Protected Health Information" as that term is defined and set forth in 45 C.F.R. § 160.103, for which special protection from public disclosure and from any purpose other than prosecuting this Action is warranted

71. "Protected Health Information" shall encompass information within the scope and definition set forth in 45 C.F.R. § 160.103 that is provided to the Parties by a covered entity as defined by 45 C.F.R. § 160.103 ("Covered Entities") or by a business associate of a Covered Entity as defined by 45 C.F.R. § 160.103 ("Business Associate") in the course of the Litigation, as well as information covered by the privacy laws of any individual states, as applicable.

72. Any Party who produces Protected Health Information in this Litigation shall designate such discovery material "Confidential Protected Health Information" in accordance with the provisions of this Protective Order.

73. Unless otherwise agreed between counsel for the Parties, the designation of discovery material as "Confidential Protected Health Information" shall be made at the following times: (a) for documents or things at the time of the production of the documents or things; (b) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and other documents, at the time of the service or filing, whichever occurs first; (c) for testimony, at the time such testimony is given by a statement designating the testimony as "Confidential Protected Health Information" made on the record or within thirty (30) days after receipt of the transcript of the deposition. The designation of discovery material as "Confidential Protected Health

Information" shall be made in the following manner: (a) or documents, by placing the notation "Confidential Protected Health Information" or similar legend on each page of such document; (b) for tangible things, by placing the notation "Confidential Protected Health Information" on the object or container thereof or if impracticable, as otherwise agreed by the parties; (c) for declarations, correspondence, expert witness reports, written discovery responses, court filings, pleadings, and any other documents containing Protected Health Information, by placing the notation "Confidential Protected Health Information" both on the face of such document and on any particular designated pages of such document; and (d) for testimony, by orally designating such testimony as being "Confidential Protected Health Information" at the time the testimony is given or by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days after receipt of the certified transcript of the deposition.

74. Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities and their Business Associates (as defined in 45 C.F.R. § 160.103), or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated in herein. Further, all Parties that are entities subject to state privacy law requirements, or entities in receipt of information from such entities, are hereby authorized to disclose Protected Health Information pertaining to this Action to those persons and for such purposes as designated in herein. The Court has determined that disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings.

75. The Parties shall not use or disclose Protected Health Information for any purpose other than the Litigation, including any appeals. The Parties may, inter alia, disclose Protected Health Information to (a) counsel for the Parties and employees of counsel who have responsibility for the Litigation; (b) the Court and its personnel; (c) Court reporters; (d) experts and consultants; and (e) other entities or persons involved in the Litigation.

76. Within sixty days after dismissal or entry of final judgment not subject to further appeal, the Parties, their counsel, and any person or entity in possession of Protected Health Information received pursuant to this Order shall destroy or return to the Covered Entity or Business Associate such Protected Health Information.

77. Nothing in this Order authorizes the parties to obtain Protected Health Information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or any other lawful process.

XIII. Information Subject to Existing Obligation of Confidentiality Independent of this Protective Order.

78. In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party's rights are implicated, provide the third party with a copy of this Protective Order and (i) inform the third party in writing of the Party's obligation to produce such information in connection with this Litigation and of its intention to do so, subject to the protections of this Protective Order; (ii) inform the third party in writing of the third party's right within fourteen (14) days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party's

production of such information or regards the provisions of this Protective Order to be inadequate; and (iii) seek the third party's consent to such disclosure if that third party does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of fourteen (14) days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Protective Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

XIV. Miscellaneous Provisions

79. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

80. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

81. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

82. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery

Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

83. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

84. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

85. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any documents or information designated as Confidential or Highly Confidential by counsel or the parties is subject to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

IT IS SO ORDERED.

Dated: 5/15/18

/s/Dan Aaron Polster
Honorable Dan Aaron Polster
United States District Judge

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***All Cases***	**Case No.: 1:17-md-2804-DAP** **Honorable Dan Aaron Polster**

EXHIBIT A TO CASE MANAGEMENT ORDER NO. _____

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. __) that was issued by the United States District Court for the Northern District of Ohio on_____, 2018 in *In re: National Prescription Opiate Litigation* (the "Protective Order").

I agree to comply with and to be bound by all the terms of the Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Protective Order to any person or entity except in strict compliance with the provisions of the Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of the Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

Date:_____

City and State where sworn and signed:_____

Printed Name:_____

Signature:_____